

# Exhibit 7

# Anavex Life Sciences Corp.

## NasdaqGS:AVXL

### FQ1 2022 Earnings Call Transcripts

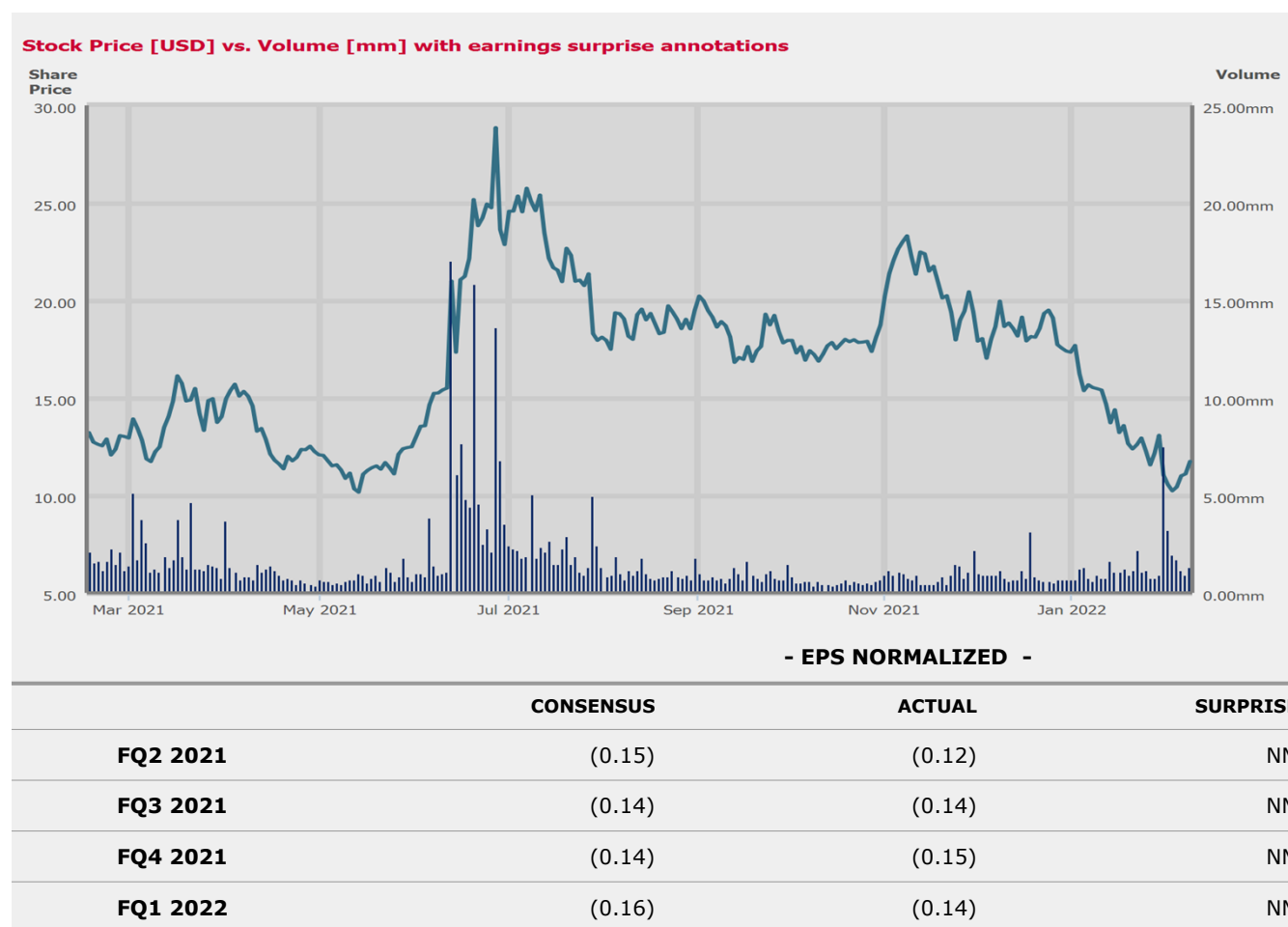
**Wednesday, February 09, 2022 9:30 PM GMT**

S&P Global Market Intelligence Estimates

	-FQ1 2022-			-FQ2 2022-	-FY 2022-	-FY 2023-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
<b>EPS Normalized</b>	(0.16)	(0.14)	NM	(0.18)	(0.76)	(0.65)
<b>Revenue (mm)</b>	0.00	0.00	0.00	0.00	0.00	7.52

Currency: USD

Consensus as of Feb-07-2022 3:09 PM GMT



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# Call Participants

## EXECUTIVES

**Christopher U. Missling**  
*President, CEO, Secretary &  
Director*

**Clint Tomlinson**  
*VP of Corporate*

**Sandra Boenisch**  
*Principal Financial Officer &  
Treasurer*

## ANALYSTS

**Charles Cliff Duncan**  
*Cantor Fitzgerald & Co., Research  
Division*

**Soumit Roy**  
*JonesTrading Institutional  
Services, LLC, Research Division*

**Tom Bishop**  
*BI Research*

**Xu Zou**

# Presentation

## **Clint Tomlinson**

*VP of Corporate*

Good afternoon. Welcome to the Anavex Life Sciences Fiscal 2022 First Quarter Conference Call. My name is Clint Tomlinson, and I will be your host for today's call. [Operator Instructions] Please note that this conference is being recorded. The call will be available for replay on Anavex's website at [www.anavex.com](http://www.anavex.com).

With us today is Dr. Christopher Missling, President and Chief Executive Officer; and Sandra Boenisch, our Principal Financial Officer.

Before we begin, please note that during this conference call, the company will make some projections and forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. We encourage you to review the company's filings with the SEC.

This includes, without limitation, the company's Forms 10-K and 10-Q, which identify the specific factors that may cause actual results or even events to differ materially from those described in these forward-looking statements. These factors may include, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital and maintenance of intellectual property rights.

And with that, I would like to turn the call over to Dr. Missling.

## **Christopher U. Missling**

*President, CEO, Secretary & Director*

Thank you, Clint, and we appreciate everyone joining us on today's conference call to review our most recently reported financial results and to provide a business update. The first quarter marked significant progress across our portfolio, highlighted by the positive top line results of the randomized placebo-controlled AVATAR Phase III study for the treatment of adult patients with Rett syndrome and the positive top line results from the placebo-controlled Phase I study of ANAVEX 3-71, which is in development for the treatment of neurodegenerative diseases, including FTD, frontotemporal dementia; and a clinical data-driven evidence of efficacy and safety of our broad SIGMAR1 platform portfolio, which allows us to plan and to expand further into the rare disease space, including implementing expanded access for adult patients with Rett syndrome, an underserved population.

At the same time, we are advancing both ANAVEX 2-73 and ANAVEX 3-71 in the planned studies with a goal to driving meaningful growth across our broad SIGMAR1 platform portfolio to deliver transformational treatments for patients with both degenerative and developmental neurological disorders around the world.

Starting with our lead drug candidate, 2-73. We reported positive top line results from the second randomized placebo-controlled AVATAR Phase III study for the treatment of adult patients with Rett syndrome. The study met its primary and secondary efficacy and safety endpoints with consistent and clinically meaningful improvements in all efficacy measures of Rett syndrome symptoms.

Convenient once-daily oral liquid doses of up to 30 milligram of ANAVEX 2-73 were also well tolerated with good medication compliance. Based on the results of the AVATAR Phase III study and the prior successful U.S. Phase II study in adult patients with Rett syndrome, Anavex is now planning to meet with the FDA to discuss the approval pathway.

Top line results from the placebo-controlled EXCELLENCE Phase II/III study for the treatment of pediatric patients with Rett syndrome are expected in second half of 2022. The extension of this expected -- or the expected duration of enrollment is based on recent country and local government requirements for

children to have full COVID-19 vaccination prior to joining a clinical trial, which includes our pediatric EXCELLENCE trial.

This Phase II/III study in pediatric patients with Rett syndrome aged 5 to 17 will evaluate the safety and efficacy of 2-73 in approximately 84 patients over a 12-week treatment period, including ANAVEX 2-73 specific precision medicine biomarkers.

Regarding our Alzheimer's disease program, top line results from the randomized placebo-controlled Phase IIb/III ANAVEX 2-73-AD-004 study for the treatment of Alzheimer's disease are also expected in the second half 2022. The 509 patients, late-stage Phase IIb/III study in patients with Alzheimer's disease is taking place at 52 sites across North America, Europe and Australia, using ADAS-Cog for cognition and ADCS-ADL for activities of daily living and function as primary endpoints.

This clinical trial is measuring efficacy, tolerability and safety of 2 different once-daily oral 2-73 doses or placebo. The current data allows us to expand in parallel our Anavex platform pipeline using gene biomarkers of response, applying precision medicine for neurological disorders with unmet medical needs, which are expected in 2022.

That includes the planned initiation of ANAVEX 2-73 imaging-focused Parkinson's disease clinical study; a planned initiation of a potential pivotal Phase II/III study in Fragile X syndrome, the most frequent genetic cause of autism spectrum disorder; and a planned initiation of a Phase II/III clinical trial for the treatment of a new rare disease indication. As well, last month, Anavex reported positive top line results from the placebo-controlled Phase I ANAVEX 3-71 clinical trial in development for the treatment of neurodegenerative diseases, including FTD, frontotemporal dementia, for which ANAVEX 3-71 has been granted orphan drug designation by the FDA.

The study reached primary and secondary endpoints of safety with no serious adverse events or dose-limiting toxicity observed. ANAVEX 3-71 was well tolerated in all cohorts receiving ANAVEX 3-71 in single doses ranging from 5-milligram to 200-milligram daily with no serious adverse events and no significant lab abnormalities in any subject.

Based on these results in ANAVEX 3-71's preclinical profile, we intend to advance 3-71 into a biomarker-driven clinical development dementia program for the treatment of FTD, frontotemporal dementia, schizophrenias and Alzheimer's disease, evaluating longitudinal effect of treatment with ANAVEX 3-71. We believe that the results of these studies could serve as the basis for advancing into respective registration studies in the U.S.

And now I would like to direct the call to Sandra Boenisch, Principal Financial Officer of Anavex, for a brief financial summary of the recently reported quarter.

**Sandra Boenisch**

*Principal Financial Officer & Treasurer*

Thank you, Christopher, and good afternoon to everyone on the call. Our cash position at December 31, 2021, was \$151.1 million, which we believe is sufficient cash runway to fund operations and clinical programs beyond 2025.

For the first quarter, cash utilized in operations was \$3.5 million. We reported a net loss of \$10.9 million for the quarter or \$0.14 per share, inclusive of noncash compensation charges of \$3.9 million compared to net loss of \$7.9 million or \$0.12 per share, inclusive of noncash compensation of \$0.9 million for the comparable quarter of fiscal 2021.

Our research and development expenses for the first quarter of fiscal 2022 were \$8.7 million as compared to \$7.9 million for the first quarter of fiscal 2021. General and administrative expenses were \$3.1 million compared to \$1.5 million for the comparable quarter of fiscal 2021.

In both cases, the increases are primarily related to an increase in noncash compensation charges of \$1.7 million for research and development and \$1.3 million for general and administrative expenses

period-over-period. These increases in noncash compensation are mainly driven by the addition of staff to manage and support our clinical studies and development.

Thank you, and I'll turn it back over to Christopher.

**Christopher U. Missling**

*President, CEO, Secretary & Director*

Thank you, Sandra. Again, we look forward into 2022. We are very excited about the company's potential as we build on the successful completion of 2 important studies that allow us to confidently expand further into the rare disease space and plan expanded access for adult patients with Rett syndrome, while we are looking forward to further pivotal clinical trial readouts in pediatric Rett syndrome and Alzheimer disease and pipeline updates this year.

I would like now to turn the call back to Clint for Q&A.

# Question and Answer

**Clint Tomlinson**  
*VP of Corporate*

[Operator Instructions] And our first question is coming from Charles Duncan with Cantor Fitzgerald.

**Charles Cliff Duncan**  
*Cantor Fitzgerald & Co., Research Division*

Let's see. Can you hear me?

**Clint Tomlinson**  
*VP of Corporate*

We can hear you.

**Charles Cliff Duncan**  
*Cantor Fitzgerald & Co., Research Division*

Okay. Super. I had a couple of questions on the recent AVATAR readout, one on EXCELLENCE, and then I wanted to ask Sandra a little bit about the cash runway.

So regarding AVATAR, we were quite intrigued with recent results. But I guess I'm wondering if you had assessed just simply the change from baseline in RSBQ and CGI and if you intend to present that data here in the near term. And then regarding the expanded access, is that part of an open-label extension study or open-label extension to the AVATAR study?

**Christopher U. Missling**  
*President, CEO, Secretary & Director*

Right. So get me -- first on the last question, the idea is expanded access is to provide not only for those patients which have been participating in the trials to give the drug for free so they can continue to enjoy the treatment effect, but also those patients which are not part of the trial. So that is the definition of the expanded access. So that's what we are considering and working towards.

Regarding the first question, let me explain again the background of the response analysis. And the results of the animal studies for Rett syndrome and other neurodegenerative diseases indicated that ANAVEX 2-73 has both symptomatic and disease-modifying effects on neurodevelopmental and neurodegenerative diseases. And for that reason, the ANAVEX 2-73 analysis of the data should capture this kind of effect. And this is done in the form of the way we have presented it as a response analysis with the RSBQ AUC.

Now on top of that, we have seen and we've learned in the paper, which was quoted and explicitly mentioned also in the presentation of February 1, pointed out that RSBQ alone as a stand-alone has just so many flaws that has, for example, 200 percentage upswing and downswing and is not calibrated in a baseline. So it's just not fair to use it.

Whatever -- however, what we can say is that we make a reference of what is the CGI requirement of a 1 point scale improvement, which is a 3 or less, which is a minimum improvement of clinical significance. And that represents a RSBQ change of average of 12.5 reduction of the RSBQ scale.

So knowing now that you have above average -- over 72% responder, which are better than 3 -- score of 3, so they can have also a score of 2, which we have seen in this study. So you can see that the RSBQ average needs to be at least more than 12.5 delta. So I hope that helps to explain this a little bit better.

**Charles Cliff Duncan**  
*Cantor Fitzgerald & Co., Research Division*

It does, Christopher. I appreciate that, and definitely appreciate linking RSBQ to clinical benefit.

Let me turn to EXCELLENCE. I guess I'm wondering if you'll use the same evaluation as was used in AVATAR because I think clin trials has it a little bit different, and you might correct that.

And then the second thing about EXCELLENCE is that in terms of the patient enrollment to date, can you give us some color on the number of patients enrolled? And when during the second half of '22 you would anticipate that study to read out?

**Christopher U. Missling**

*President, CEO, Secretary & Director*

Yes. So the enrollment is going well. It's just that we learned that because of the COVID vaccines have been approved around the world and also have been approved for children, which are younger than 18, and the requirement is now that all these participants want to and need to and it's a fair proposition to get vaccinated.

The protocol, however, requires that you have to be on a constant medication several weeks, I think it's 6 or 8 weeks in advance, before joining a trial. So that means that you have to get the first dose of the vaccine but also the second one. And in time -- and then you have to allow for some time to pass by to be on a stable new indication -- new medication, and vaccine is a new medication. So what it does, it shifts a little bit out the time line to finish the last patients in this trial. The -- what was the other question, Charles? I just...

**Charles Cliff Duncan**

*Cantor Fitzgerald & Co., Research Division*

Yes. I just -- I was just wondering if you can provide some color on the number of patients enrolled thus far.

**Christopher U. Missling**

*President, CEO, Secretary & Director*

We are doing well from our perspective. I'd like to just mention that right now, we are very comfortable with the time frame during second half '22 that gives us amply -- ample time to complete the study with this additional required vaccination regimen. So this is sufficient for us at this point to share.

**Charles Cliff Duncan**

*Cantor Fitzgerald & Co., Research Division*

Okay. And you may narrow the time frame from, say, second half to a little bit more granularity in the future as your enrollment progresses?

**Christopher U. Missling**

*President, CEO, Secretary & Director*

Exactly right. Yes. And in regards to the ClinicalTrials.gov, I would like to make, again, a statement here that the ClinicalTrials.gov is not what we want to refer as to company communication. It will be updated eventually. So I'd like to -- you to be aware of that. So the company communication is -- has priority over ClinicalTrials.gov, but it will be updated when we have finalized the study outcome. And then we will also update the ClinicalTrials.gov. Right now, it might not be completely up to date. So I want to make sure people understand that.

**Charles Cliff Duncan**

*Cantor Fitzgerald & Co., Research Division*

Okay. Last quick question for Sandra. I think you mentioned \$151 million go through '25. I assume that's considering only the current spend and that you are not contemplating an NDA filing or commercial prep for that runway and that the runway may change if you end up being involved in an NDA filing and/or commercialization?

**Christopher U. Missling**

*President, CEO, Secretary & Director*

Yes. If I can maybe start first. So we have over \$150 million in cash, which is a really incredibly large sum of money. And when you calculate our average cash utilization in the past was very consistent in the range of \$2 million per month to \$2.5 million. And now in the last quarter, we averaged \$2.3 million, I think.

So this exactly right will be the cash utilization. If we do have additional plans, which are marketing the drug, of course, there will be a difference in that regard. So in this regard to the cash utilization is right now continuing what we have planned, which is the several studies, which we mentioned we are planning to do and executing the studies which are ongoing. So that is the assumption of the calculation.

**Clint Tomlinson**  
*VP of Corporate*

The next question is coming from Soumit Roy at Jones Research.

**Soumit Roy**  
*JonesTrading Institutional Services, LLC, Research Division*

Congrats on this quarter and the data. One question, Chris, I wanted to understand or get your take on, how do you think FDA would look at 2 drugs being filed so close to each other with 2 different endpoints? Curious if you would make any comment if you think they would ask Acadia to file it RSBQ AUC?

**Christopher U. Missling**  
*President, CEO, Secretary & Director*

It's an excellent question. I would like to speak just on our data. We really think that, as I mentioned before, every drug needs to be looked at in its uniqueness, and you want to analyze it with the drug effect in mind. And that's what we've done.

And on top of it came the paper on the RSBQ, which really has extremely high variability and baseline inconsistency. And again, I'm not speaking here out of line. It's really in this paper from 2020, which came around the time when we finished our first study in the U.S. study. And that's what we learned from that to adjust to this.

And then the guidelines of the FDA guidance are really specific, what to do in those cases. If you have a baseline -- if you have an endpoint, which has not a totally reliability feature, then you can use what is called the anchoring and use the response analysis.

But that requires -- it's very important, and we probably should highlight it stronger that this endpoint in question needs to be correlating with the CGI. And if it doesn't correlate, you cannot use this anchoring method. So -- and you are then left with a poor outcome.

But since we tested the correlation, and it should correlate because the difference between the 2 measures are the RSBQ is assessed by the parents, and the CGI are assessed by the physician. And while they measure different things, they both should basically see a positive change independently of each other. And so that means they should eventually correlate to a certain extent. And they do in our studies, and they did in those studies, which is a good thing.

And so once you have established a correlation, then the FDA guidelines really explicitly say, please use this anchor-based method because you just also take care of what the FDA is always concerned about not clinically -- not statistical significance, but clinically meaningfulness. And by doing this, we basically raised the bar for us, for the drug. But we also did it to make it easier to appreciate the drug effect because now you can be assured that everybody who's a responder also has to have an improvement, which is clinically meaningful.

So we made it for the FDA easier. That's why I think the guidance is very clear because they want to make sure that you just don't have an average statistical improvement of a certain percentage and/or score, but it doesn't mean anything to anybody. Nobody can confirm that it is beneficial. The physician cannot assess it or confirm it. The patient cannot confirm it, and the parents cannot confirm it, but it's statistically significant. So it doesn't help anybody.

So by using this approach of the CGI anchored RSBQ, you'll see we were able to raise the bar, make it easy to interpret. So it's the analogy of what we just also mentioned on the 1st of February of the story of the way skin diseases are assessed in rash or other features that you have to raise -- reduce a certain amount, a minimum amount. For example, in rash, it's at 75% or even 90% before being considered even that the drug works. And this bar is what we have here included. And that allows for just more fair and proper assessment of the drug -- of the effect of the drug.

**Soumit Roy**

*JonesTrading Institutional Services, LLC, Research Division*

Chris, that really helps. One last question is, if you can remind us if there is any formulation difference between the adult Rett trial and the pediatric one? And if you could talk about if the liquid versus pills you see any advantage you have versus your peers?

**Christopher U. Missling**

*President, CEO, Secretary & Director*

Yes. So we have for the Rett trials consistent liquid formulation across all trials, all 3 trials in the program. So the U.S. study, the AVATAR and the EXCELLENCE, have exactly the same formulation. It's a liquid formulation once daily orally, they take the amount of drug they need. And so there's no difference.

What maybe you are referring to is the formulation for the Parkinson's disease, dementia study and the Alzheimer disease study. So in those cases, we have a once-daily solid capsule formulation or pill. And that is obviously also at different doses, and that is taken in a solid form.

And the reason why we formulated or developed a formulation of liquid formulation of the drug was we learned very early on that patients with Rett syndrome sometimes either cannot swallow capsules or pills or they have not even the ability to take food or a liquid the normal way. They have a pouch, where they have basically getting that injected. So you need to have a formulation which allows to do that, and a liquid formulation is exactly suitable for that.

**Clint Tomlinson**

*VP of Corporate*

The next call is coming from Tom Bishop at BI Research.

**Tom Bishop**

*BI Research*

Can you hear me?

**Christopher U. Missling**

*President, CEO, Secretary & Director*

Yes.

**Tom Bishop**

*BI Research*

Okay. If memory serves me, on another call, you estimated that, I think, that the total Rett market could be as much as \$2 billion to \$5 billion. And I was just wondering if my recollection is correct. And was that for the U.S. or the world? And maybe even if you can tell us something about the adult Rett population versus the pediatric.

**Christopher U. Missling**

*President, CEO, Secretary & Director*

Right. So the number, I don't think we mentioned it, but is back-on-the-envelope calculation, which I just want to point out here. So on average, there are 11,000 patients assumed in the U.S., so let's simplify 10,000. And a rare disease pricing per year could be easily in the range, and I'm not saying that this is the price of the drug for Rett patients, but it could be in the range of \$200,000 to \$500,000 per year per

patient. And if you calculate and multiply this by 10,000, so the total revenue per year could be sales in the range of \$2 billion to \$5 billion. I think that's probably the calculation was made. So that would be addressing only U.S. market at this point.

If you also now look at specific to adult patients with Rett, we estimate this is around about 50% of the patients in the -- of adult patients compared to the total patient amount. So you basically would assume that the adult Rett population would be around about half of that.

**Tom Bishop**  
*BI Research*

Okay. And then there's the whole world to boot.

**Christopher U. Missling**  
*President, CEO, Secretary & Director*

And then there's whole world. We have -- obviously, the markets are large. What we have seen is that the market sizes are in the range of, I would say -- what have we seen in -- an estimate Fragile X, Europe is 13,000, Asia is 37,000 and global 350,000.

**Tom Bishop**  
*BI Research*

Was that Fragile X or Rett?

**Christopher U. Missling**  
*President, CEO, Secretary & Director*

Yes, this is -- sorry, this is Rett syndrome only. So Rett syndrome, Europe is 11 -- 13,000. These are all quoted references from the national foundations or respective information. And Asia's 37,000 Rett syndrome patients and global 350,000 patients with Rett syndrome. Fragile X is larger. It's around about 6 to 7x the size of Rett syndrome.

**Tom Bishop**  
*BI Research*

Okay. I note that the quarterly commentary, again, skips over Parkinson's disease dementia and the physical aspect as well. And I'm wondering why that is. And what's the status?

**Christopher U. Missling**  
*President, CEO, Secretary & Director*

No. We want to update when we have the updates. So the PDD study was really successful, and it allowed us to move into now 2 directions. And we stated that. One is to plan a potentially pivotal study in Parkinson's alone given the strong UPDRS signal as well as in UPDRS in Parkinson's disease dementia given the strong cognitive improvement.

We are now discussing with the respective experts designs of such studies. And then we go with these designs to the FDA, to the agency and ask for their input on how to execute those studies, and that's right now taking place. So once we have feedback, we will come back and revert back on this.

**Tom Bishop**  
*BI Research*

Good. Okay. And when do you estimate the last patient will complete the last observation in the 48-week Alzheimer's trial? I understand that's fully enrolled at 509,000 -- 509 patients already, right?

**Christopher U. Missling**  
*President, CEO, Secretary & Director*

Yes, 509 patients. So we expect the last patient to be finished around probably summertime. And so I think then we have to clean data and do data lock, and then we have the data. So that's right now the expected time lines.

**Tom Bishop**  
*BI Research*

Could you just describe the various steps of activities after the trial is over and the cleaning and eventually then blinding the trial and crunching the numbers? I mean how long do these -- what are these various steps? I think it would help everybody a little bit. And how long roughly -- a time range roughly do they take?

**Christopher U. Missling**  
*President, CEO, Secretary & Director*

Right. So the key bulk of the time is the data cleanup. So you have to be aware that a clinical trial once it's data locked, what it's called, you cannot go in there anymore. You cannot even change a comma. It's like locked as the word says.

So what you want to do, you want to double, triple, quadruple check every entry, that all the entries are in there, that all items are explained, that there's no missing cell or whatever, like an Excel spreadsheet. So this -- everything needs to be checked and double checked and triple checked. And that often takes several months.

And once it's done, it's locked and then the time from lock to the unblinded data is very short. It's 2 weeks because then the CRO does that, and they do quality control themselves to double check that the outcome is truly what they have -- the calculation is provided, and they double check with their own internal control. And then they give it to us. So this is around about how it works.

**Tom Bishop**  
*BI Research*

Okay. That's helpful. And there have been a lot of estimates of how big the revenue opportunity would be for a drug that works on Alzheimer's disease, and I must confess to have made some myself in the U.S. and the world. And for the U.S., I think it sounds to me like many think that could be around \$10 billion annually. But I'm more interested in what your thoughts are on that market potential size.

**Christopher U. Missling**  
*President, CEO, Secretary & Director*

Yes. I mean, it's certainly not out of reach or unreasonable. I remember when the data or the approval from Biogen was announced that the stock jumped to \$30 billion. So if that is the expectation of net present value of a successful trial -- potential successful drug can then go to market, then so be it.

And I think it's really like a measure of price times patients which are eligible. And then you have to make the math from that point of view. But certainly, it's a largest unmet need. There's no doubt about that.

**Tom Bishop**  
*BI Research*

I noticed that same \$20 billion increase in the market cap of Biogen temporarily, anyway.

**Christopher U. Missling**  
*President, CEO, Secretary & Director*

We have here another question if there is no other question. I was wondering if you could comment on a couple of items. Will you consider initiating further trials in Angelman syndrome, perhaps a basket trial with multiple gene-related disorders.

And so the answer to that question is we are planning already -- so let me ask this -- answer this. So we want to basically bring home the Rett franchise first, and we're very close to that. And after that, we

want to tackle these other indications, which we have preclinical data, information which is a conducive of moving into a clinical trials, which includes Angelman syndrome.

But also, as I mentioned, I think, on the last call that we are planning to use a quasi-basket trial for Fragile X because Fragile X is a very heterogeneous population. And we just wanted to make sure we're addressing the right population for the cohort. And what we do, we do a quasi -- planning a quasi-basket trial in Fragile X. So each cohort will be addressed and will be homogeneous. We are assessed by how well they do with our drug. So we're already basically utilizing this basket-like trial designs to feature in our next trial. Clint, are there any more questions do you see?

**Xu Zou**

Okay. Can you hear me?

**Clint Tomlinson**

*VP of Corporate*

Please go ahead, yes.

**Xu Zou**

Okay. This is Xu on for Yun. Congratulations on this quarter's progress. And I just want to take 1 step back about the Rett syndrome clinical manifestation because Rett syndrome, that has pretty wide range of clinical manifestation. So do you consider Rett syndrome primarily central nervous related or both central and peripheral? Because a lot of multiple clinical trials have been using RSBQ and CGI as their primary endpoint. But some experts believe RSBQ focus too much on behavior changes, but motor functions for Rett syndrome patients are also important. So are you marrying any like motor function-related endpoints in the trial?

**Christopher U. Missling**

*President, CEO, Secretary & Director*

Excellent question. And that's another reason why the RSBQ is basically not a bad endpoint, but just needs to be put in the right perspective, and as a stand-alone, not sufficiently validated to represent the full features of Rett pathology.

So the answer to that is twofold. Yes, we did see a signal also in movement features. We noticed that in the quality-of-life assessment that there were some activities noticed in that regard, and the quality of life also captures movement.

And also, for example, family cohesion. So is the family more happy to deal with things? And can the patient do things by itself? And we also heard from some investigators that there were the ability of moving the legs again which were not able to move before.

And to come to the question about the periphery versus central nervous system, I think this is a complex disease. And as we learn more about it, we also have to appreciate that the fact that we have seen in the periphery by measuring blood biomarkers of pathology like the GABA and the LAAA, which responded nicely and were in line with the outcome of the patient benefit.

So these are also CNS-related features, but they were measured in the periphery. So we cannot exclude that the periphery effect also is involved. But ultimately, we know that the key feature of the drug is really on CNS. And we have seen that confirmed with the target engagement study we did prior with the PET scan sigma-1 ligand.

So we definitely know that the key target point is in the brain. But again, I would not exclude that there is also potential periphery effect, but the key target is definitely the CNS.

**Xu Zou**

It's helpful. So regarding your interaction with the regulators, have you already scheduled a meeting with the FDA? Or when should we expect to see?

**Christopher U. Missling**

*President, CEO, Secretary & Director*

Yes. So the way it works, we have to send to the FDA clinical trial reports, and they're required to be put together. So it's not just the slides which we have. So in that right now is on the high pressure is taking place. So once we have those slides, those documents done together, which are clinical study reports, the formal report, then we will submit them and then request the meeting.

**Xu Zou**

Okay. So do you expect the feedback to be before the readout of EXCELLENCE study?

**Christopher U. Missling**

*President, CEO, Secretary & Director*

This is very likely because we said second half of 2022, so we expect that to be the case, yes.

**Xu Zou**

Okay. Sure. Second follow-up, your -- you just mentioned your basket study for 3-71 for 3 different indications. Just can you give us more color on like 3 different indications, how do you plan to recruit the patients and how to measure efficacy, this indication have very different endpoint or clinical duration like [indiscernible] change very quickly. So do you have any prioritization or just give me color on that.

**Christopher U. Missling**

*President, CEO, Secretary & Director*

Right. So I think it was a bit of like maybe explained too quickly. We refer to Fragile X where we will include Fragile X patients. These are all Fragile X patients, but they have different features which are not identical. So they have to homogenize them to make them more consistent in their feature. We group them in distinct groups of Fragile X. And it could be certain behavior prevalent -- certain cognitive impairment prevalences and so forth. So that's what I was referring to do across the basket trial. So we will measure the same endpoint, which is Fragile X-related endpoints.

When it comes to ANAVEX 3-71, which we are planning in Alzheimer in frontotemporal dementia and also schizophrenia, this will be not basket trial. It will be in a program, call it. There will be trials which will be done separately because schizophrenia, for example, requires a relatively short study duration, run about 6 weeks, for example. In the FTD and Alzheimer study require longer studies, at least 6 months. So you see already from that angle that they are not -- that they cannot be put in one trial together.

**Clint Tomlinson**

*VP of Corporate*

That's all the questions, Dr. Missling.

**Christopher U. Missling**

*President, CEO, Secretary & Director*

So then we'd like to thank everybody. And again, as we look forward into 2022, we're very excited about the company's potential as we build on a successful completion of the 2 important studies that allow us to confidently expand further into the rare disease space and plan expanded access for adult patients with Rett syndrome, and while we're looking forward to further pivotal clinical trial readout in pediatric Rett syndrome and in Alzheimer's disease as well as pipeline updates this year. So with that, thank you very much.

**Clint Tomlinson**

*VP of Corporate*

Thank you, ladies and gentlemen. And that concludes today's conference call. We appreciate you participating. You can now disconnect.

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